

Policy Statement

The Laboratory Response Network

Policy Regarding Evaluation of Laboratories for Entry into Confirmatory Levels of the Laboratory Response Network

October 17, 2003

Policy Statement:

1. It is the policy of the Laboratory Response Network (LRN) to strengthen and provide direct support to the nation's federal, state, and local public health laboratories in their effort to prepare for and respond to acts of bioterrorism or other public health emergencies.
2. This policy can only be furthered through the partnership of the Centers for Disease Control and Prevention (CDC) and APHL and its members, and their collective adherence to the terms of this policy.
3. At the center of the LRN are State Public Health Laboratories (SPHLs) and their Directors (SPHLDs) that provide critical support and services within the public health laboratory infrastructure, and serve as confirmatory laboratories for front-line sentinel laboratories (whether public health or non-public health labs).
4. The mission of the LRN can only be served when its resources (including protocols, reagents, and communications systems) are secure. Non-public health laboratories should not be admitted to the reference level of the LRN unless their entry is demonstrated to be essential to meet a specific state need for increased laboratory capability or capacity.
5. If the SPHLD, based on an assessment of response capacity within the state, determines there is a specific need for additional support from a non-public health laboratory to meet the emergency response mission of the state, the SPHLD may recommend consideration of a non-public health laboratory to the LRN.
6. A non-public health laboratory may become part of the state confirmatory testing network of the LRN only if:
 - a. The specific criteria in A.1 below are met by the state and by the proposed non-public health laboratory;
 - b. The SPHLD specifically recommends that the proposed non-public health laboratory participates in the LRN;
 - c. The proposed non-public health laboratory agrees via contract to all of the provisions stated in A.2 below; and
 - d. The proposed non-public health laboratory director obtains written affirmation of the approval of the SPHLD prior to engaging in any proposed activities.
7. Any non-public health laboratory that fails to meet the criteria or processes above may not become or be considered part of the reference level of the LRN by any of its participants.
8. Membership evaluation criteria for the public health laboratories at the confirmatory level are established through the existing Due Diligence review process. A copy of this document is available through the LRN helpdesk or APHL.

A. Analysis of Clinical Specimens

Since the mission of the LRN can only be served when its resources (including protocols, reagents, and communications systems) remain secure within the system, States should not seek to add non-public-health laboratories to the LRN unless their entry is demonstrated to be essential to meet a state need for increased laboratory capability and/or capacity. The SPHLD, in consultation with other senior state health officials, may identify a need for additional clinical testing capability and/or surge capacity that can only be met by entry of a laboratory other than a state or local public health laboratory into the secure, confirmatory level of the Laboratory Response Network (LRN).

State Public Health Laboratory Directors are urged to consider the unique hazards accompanying a laboratory response to terrorism or other public health emergencies, to carefully consider the ability of non-public health laboratories to manage these risks, and to explicitly communicate this concern to representatives of such candidate laboratories.

In contrast to naturally occurring disease, victims of terrorist events may have multiple exposures to biological, chemical, radiological, toxic and other agents. Required specimen handling, packing, shipping, processing and chain-of-custody procedures must be strictly adhered to by participating laboratories, and the challenges of assuring the safety of the laboratory worker must be fully understood and addressed.

A.1 Evaluation Criteria

The SPHLD is the state-based gatekeeper for entry into and maintenance of all state and local government and private or academic laboratories at the confirmatory LRN level within the state. Appropriate federal departments and agencies are the gatekeepers for entry into and maintenance of all federal laboratories within the confirmatory LRN level. SPHLDs are not vested with the authority to approve federal laboratories within the confirmatory LRN level. Correspondingly, federal departments or agencies may recommend, but are not authorized to approve, the entry of a confirmatory laboratory (whether public health or non-public health) into the state confirmatory LRN level.

Only through a decision and formal approval by the SPHLD may a laboratory be admitted into the state confirmatory LRN level. For this decision and approval to be made by the SPHLD, the laboratory seeking entry, must meet the following criteria:

1. Facility and personnel security: Must conform to existing requirements of the Select Agent Rule, USA PATRIOT Act of 2001, and BMBL 4th edition, Appendix F, or other superceding document.
2. Reagent controls: per LRN policy, there will be no distribution of any LRN assets or materials outside of the receiving facility to which the LRN originally supplied the material.
3. Worker safety: Must conform to BMBL 4th (or current) edition facility and practice criteria recommended for the agent(s) to be tested, including vaccination of workers when appropriate.
4. Licensure/ certification: Must be currently certified according to the Clinical Laboratory Improvement Amendments of 1988, and applicable state licensure requirements.
5. Data and Information Security: Must meet the requirements of HIPAA in managing clinical specimens and results. Once in the LRN, must restrict access to protocols, reagents, samples

and results only to those personnel previously approved for access to the secure LRN Website.

6. Reporting: Must agree to provide results of any and all testing performed with LRN protocols and reagents directly to the SPHLD.
7. Proficiency: Must agree to participate in CAP, SPHL or CDC-sponsored proficiency testing, and demonstrate proficiency.
8. Specimen Handling: Must have sample transport and chain of custody procedures in place that conform to IATA, DOT and law enforcement requirements.
9. Regulatory Restrictions: Must understand and accept the regulatory restrictions and liability on the use of specialized public health biodetection assays which are not intended for diagnostic use outside of LRN defined testing parameters, especially regarding liability concerns if used as unapproved in vitro diagnostic tests for individual patient management decisions.
10. Federal Acquisition Regulations (FAR): Must comply with existing guidelines and restrictions related to the use of federal funds under the FAR, especially when a contractual (funded) relationship is required.

A.2 Contractual Obligations

In situations in which the SPHLD determines the need for entry of an additional laboratory into the confirmatory level of the LRN, a detailed operational plan, including defined roles and responsibilities and SPHLD-approved sources of funding, must be developed and approved by mutual agreement between the SPHLD and the director of the laboratory under consideration.

As a general guideline, LRN resources (including protocols, reagents, and proficiency testing) must only be used by the laboratory at the explicit request of, or after consultation and subsequent approval by, the SPHLD, and not as routine practice. In addition, FAR Part 31 requires that if a private-for-profit entity receives federal funds to purchase equipment or upgrade facilities pursuant to an agreement with the SPHLD, the entity may only use such equipment or facilities for the activities within the scope of the contract.

The preference is for confirmatory testing of specimens to be done at the SPHL unless this function is delegated by the SPHLD to the non-public health laboratory in response to a specific situation. To maintain the security of the confirmatory level of the LRN, the SPHLD, prior to admitting an additional laboratory, must obtain the written consent of the director of the laboratory under consideration attesting to the compliance of the laboratory with the following:

1. Must agree to use only LRN protocols and reagents when conducting confirmatory testing of suspected terrorism agents or “special pathogens” that may be occurring naturally and be causative of a public health emergency.
2. Must agree to use LRN reagents only for testing of suspected terrorism agents, not for research, development, or private, for-profit testing. Must agree to use LRN protocols and reagents only within the scope identified for that laboratory and as outlined in the contract with the laboratory.
3. Must agree to provide results of any and all testing performed with LRN protocols and reagents directly to the SPHLD.
4. Must agree to limit copying and distribution of LRN protocols to those parties who will actually conduct confirmatory testing during a terrorism event or other public health emergency and who were previously approved for access to the secure LRN Website.
5. Must agree to provide 24/7 services when requested by the SPHLD during a terrorism event or other public health emergency.

6. Must immediately report positive results to the patient's healthcare provider(s) in accordance with state and federal disease-reporting requirements; must not release test results to any other parties.
7. Must agree to assume liability resulting from use of any LRN reagents that have not been approved by FDA for use for human clinical testing.
8. Must immediately implement chain-of-custody procedures meeting standards of evidence in the jurisdiction, and reviewed in consultation with the state FBI Weapons of Mass Destruction Coordinator, when a terrorist event is suspected. Must be willing to provide expert witness testimony concerning tests conducted during a terrorist event.
9. Must agree to dissolution of the contract by the SPHLD without cause, immediately upon notice, and to surrender any and all LRN reagent stocks, Select Agents, protocols and equipment immediately should liability based on fault occur.

B. Analysis of Environmental and Food Specimens

Criteria for entry of additional laboratories into the confirmatory level of the LRN for testing of environmental and food samples are under development and are not available at this time. However, an existing statement of relevant policy and a statement of concern developed during discussion are articulated below.

To avoid the possibility of laboratory contamination and resultant disruption of patient services, the LRN Working Group determined in July 2002 that **clinical laboratories should not accept environmental samples for biological or chemical agent testing**. APHL and CDC, as principal partners in the LRN, have agreed not to support, pursue, or fund the entry of clinical laboratories into the LRN for the purpose of conducting environmental or food testing related to terrorist events. While the Working Group did not explicitly address it, this concern would also apply for testing of environmental samples by veterinary laboratories.

Terrorism-related environmental samples present even greater concerns for worker safety than do clinical specimens. SPHLDs should expect that samples delivered by law enforcement or HazMat teams may contain multiple hazards. SPHLDs **are urged to consider the unique hazards accompanying a laboratory response to terrorism, and to carefully consider the ability of non-public health laboratories to manage these risks**. Sample handling, packing, shipping, processing and chain-of-custody procedures must take this into account, and the challenges of assuring worker safety must not be taken lightly.

Federal entities cannot add state capacity for environmental and food samples without the consultation and approval of the State Public Health Laboratory Director.